

Request for Reconsideration:

Applicants are amending claim 9 to include the limitations of independent claim 1, claim 16 to include the limitations of independent claim 12, and claim 22 to include the limitations of independent claim 19. In view of the Office Action's indication of allowability, these amendments render claims 9-11, 16-18, and 22-24 allowable. Further, Applicants are amending claims 1, 12, 19, and 43 to more specifically describe the first and second "means for securing fixing sutures" of the first and second cylinders, respectively, as "securing fixing sutures therebetween." Because Applicants are cancelling claim 42 and withdrawn claims 4, 6-8, and 25-40, without prejudice; no excess claim fees are due as a result of these amendments. As a result of the foregoing amendments, claims 1-4, 9-24, and 43 are pending in this application. No new matter is introduced by these amendments, and these amendments are fully supported by the disclosure. Applicants respectfully request that the Examiner enter these amendments and reconsider the above-captioned patent application in view of the foregoing amendments and the following remarks.

Remarks:

1. **Objections and Rejections.**

Applicants acknowledge with appreciation that the Examiner has not renewed his previous objections to claims 42 and 43 and that the Office Action now indicates that claims 9-11, 16-18, and 22-24 contain allowable subject matter and would be allowable if rewritten in independent form to include the limitations of their base claims and any intervening claims. Nevertheless, the Office Action rejects claims 1-3, 12-15, 19-21, and 42 and 43 under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 5,766,240 to Johnson.¹ The Examiner has made these rejections **final** by this Office Action. Applicants respectfully traverse.

2. **Anticipation Rejections.**

Claims 1-3, 12-15, 19-21, and 42 and 43 stand rejected as allegedly anticipated by Johnson. "A claim is anticipated if and only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. . . . [Moreover, 't]he identical invention must be shown in as complete detail as is contained in the . . . claim." MPEP 2131 (emphasis added; citations omitted). Applicants respectfully traverse these rejections.

Referring to Johnson's **Figs. 7-9**, the Office Action contends that

Johnson discloses an apparatus comprising: a first cylinder (120) having first and second ends, the second end having an adjacent exterior lip (120.1) for securing to an interior groove (130.6) on a second cylinder (130). Johnson also discloses an apparatus comprising: a first cylinder having first and second ends, the second ends, the second end having an adjacent exterior annular groove for securing to an interior lip on a second cylinder (Figs. 7 and 8). The first cylinder has a fabric annular cuff surrounding the exterior surface adjacent to the first end. The first and second securing means of Johnson are **capable** of "fixing sutures therebetween", and therefore meet the structural limitations.

Office Action, Page 3, Lines 9-17 (bolding in the original). In fact, Johnson's "annular cuff," to which the Examiner refers, is suturing ring (14, 140), and entirely surrounds Johnson's "second

¹ Claims 4, 6-8, and 25-40 are withdrawn from consideration as directed to an unelected group. Nevertheless, the Examiner now has considered previously withdrawn claims 3, 14, 21, and 42.

cylinder (130).” In view of the foregoing amendments and for the reasons set forth herein, Applicants respectfully traverse.

Applicants maintain that the Office Action fails to demonstrate that Johnson anticipates Applicants’ claimed invention for at least three reasons. **First**, Applicants previously remarked that Johnson does not disclose (or suggest) and the Office Action does not contend that Johnson discloses the fixing of sutures between “first cylinder (120)” and “second cylinder (130).” Thus, the Office Action fails to demonstrate “that each and every element as set forth in the claim is found, either expressly or inherently described, in [Johnson]. MPEP 2131 (emphasis added). As noted above, the Office Action does not allege that Johnson “expressly” discloses that Johnson’s “cylinders” are “adapted to secure fixing sutures therebetween,” but Applicants maintained that this feature of the claimed invention also is not “inherently” described in Johnson.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. . . . “To establish inherency, the extrinsic evidence ‘must make the clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’”

MPEP 2112(IV) (emphasis in original; citations omitted). Applicants maintained that the Office Action has not provide evidence to show that Johnson “necessarily” is “adapted to secure fixing sutures therebetween,” and that this adaptation would be “recognized by persons of ordinary skill.”

The Office Action now contends that Applicants fail to describe the fixing of sutures between the first and second cylinders in independent claims 1, 12, 19, and 43. Consequently, Applicants are amending each of these claims to more specifically describe the first and second “means for securing fixing sutures” of the first and second cylinders, respectively, as “securing fixing sutures therebetween.” Applicants maintain that the use of means-plus-function language, as well as the removal of the “adapted for” language from these

claims, makes clear that this function now is described in the claims. Therefore, each and every element of Applicants' claimed invention is neither expressly or inherently disclosed by Johnson.

Second, Applicants previously remarked that the Office Action appears to equate the phrase "adapted to" with "capable of," and that this is incorrect. Nevertheless, in view of Applicant's amendments to claims 1, 12, 19, and 43, both Applicant's previous remarks regarding this basis for rejection and the Office Action's response now are moot.

Third, Applicants previously remarked that although the Office Action alleges that Johnson's apparatus is "**capable**" of "fixing sutures therebetween" without further modification, the Examiner has not shown that persons skilled in the art would interpret Johnson is in that manner. The Office Action fails to provide any support for its assertion that Johnson is "capable" securing sutures between its split ring 130 and valve body 120. First, the Office Action does not identify any portion of Johnson's disclosure in which this alleged "capability" is disclosed or even remotely suggested. Second, each of Johnson's embodiments, as depicted in Johnson's **Figs. 3-10**, "[a]ll of the valves are characterized by having an annular valve body carrying a circumferential, rotatable suturing ring permitting rotation of the valve after the suturing ring is sutured to the valvar rim remaining after removal of a patient's diseased heart valve." Johnson, Column 8, Lines 5-9 (emphasis added). Johnson states that the valve body (12, 120) is positioned within the split ring (13, 130) and the suturing ring (14, 140),² such that

the torque required to for rotation of the valve body should be sufficiently small as to avoid rotational forces tending to loosen the sutures or damage the heart tissue which has been sutured to the suturing ring but yet should be sufficiently high as to prevent the valve body from rotating within the suturing ring when the heart function has been restored.

Johnson, Column 11, Lines 24-30 (emphasis added). Thus, Johnson only describes rotational movement between the valve body (12, 120) and the slip ring (13, 130), even when the suturing ring (14, 140) is positioned therebetween. Even if the Office Action could show that the slip ring (13, 130) and the valve body (12, 120), with the suturing ring (14, 140) therebetween, are capable of poorly securing fixing sutures therebetween, the Office Action fails to show that

² Johnson's suturing ring appears to correspond to Applicants' valve sleeve, but Applicants' valve sleeve clearly is not secured between Applicants' first and second cylinders in any disclosed embodiment. Appl'n, Paras. [0011] and [0013]; **Fig. 5**.

Johnson is "capable" of securing fixing suture, as described in Applicants' claims 1 and 43, which do not include a valve sleeve, or in Applicants' claims 12 and 19, which describe a valve sleeve which is not disposed between the first and second securing means.

The Office Action maintains that anticipation occurs as long as the prior art is "capable" of fixing the sutures, even poorly. Nevertheless, Applicants do not contend that Johnson could fix sutures only poorly, but instead that Johnson, as disclosed, is "incapable" of fixing sutures, as described in Applicants' claims. At best, the Office Action may contend that Johnson is capable of poorly securing suture between the suturing ring and the valve body, but that does not disclose Applicants' claimed invention. In view of the foregoing amendments and remarks, Applicants maintain that the Office Action fails to demonstrate that Johnson expressly or inherently discloses each and every element of the claimed invention.

In view of the foregoing remarks, Applicants maintain that the Office Action has failed to demonstrate that Johnson expressly or inherently discloses each and every element of the claimed invention. Thus, the Office Action fails to demonstrate that claims 1-3, 12-15, 19-21, and 42 and 43 are anticipated by Johnson. Therefore, Applicants respectfully request that the Examiner withdraw the anticipation rejections to these claims.

Conclusion:

Applicants respectfully submit that this application, as amended, is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that a further interview with Applicants' representatives, either in person or by telephone, would expedite

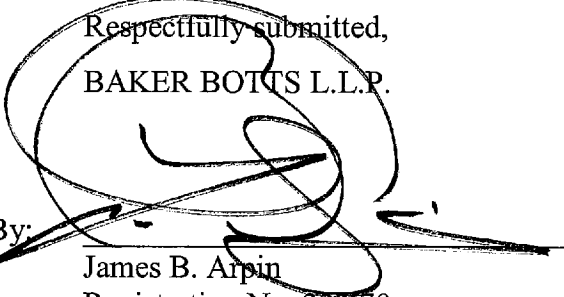
prosecution of this application, we would welcome such an opportunity.

Respectfully submitted,
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Dated: December 22, 2005

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